

Remarks

In the Office Action dated August 24, 2004, the Examiner required restriction to one of the following groups:

I-XI:	Claims 1, 3, 4, 30, and 31;
XII-XXII:	Claim 5;
XXIII-XXXVIII:	Claims 7, 8, and 32; and
XIX:	Claims 29 and 33.

At the outset, Applicants note an error with respect to the Examiner's numbering of the groups of inventions. Applicants believe that the Examiner intended to number the groups of inventions as follows:

I-X:	Claims 1, 3, 4, 30, and 31;
XI-XX:	Claim 5;
XXI-XXXVI:	Claims 7, 8, and 32; and
XXXVII:	Claims 29 and 33.

Applicants hereby elect, with traverse, the invention of group III, which corresponds to SEQ ID NO:21 and haplotype 4 in Table 5 of the specification.

Applicants submit that the Examiner's requirement for restriction to one of groups I-X and XXXVII – corresponding to the subject matter of claims 1, 3, 4, 29-31, and 33 – is improper as being contrary to well-established law. These claims are directed to a genus of naturally occurring variants of the human β_2 AR gene. A Markush group of specific nucleotide sequences defines the different isogenes within the genus, and a restriction requirement may be applied to a Markush-type claim only when the subject matter in the claim lacks unity of invention. *In re Harnisch*, 206 U.S.P.Q. 300 (C.C.P.A. 1980). "Unity of invention exists when compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility." M.P.E.P. § 803.02. Applicants respectfully submit that the subject matter of claims 1, 3, 4, 29-31, and 33 has unity of invention because (1) each of the β_2 AR isogenes share the common utility of encoding a polypeptide that can be activated by a β -agonist, and (2) each of the β_2 AR isogenes share a significant structural feature in that each isogene has an identical length of 523 nucleotides in the coding region, which is a region of the β_2 AR gene that would be considered by the skilled artisan to be structurally significant in establishing the common utility of encoding a polypeptide capable of

Docket No. MW75-0303US2

being activated by a β -agonist. Further, as seen in SEQ ID NOs:19-28, the β_2 AR isogenes of claims 1, 3, 4, 29-31, and 33 differ by a maximum of only 5 out of the 523 nucleotides in this functionally significant region, making each β_2 AR isogene at least 99% identical to the other isogenes in this region. Applicants assert that the high level of identity of the β_2 AR isogenes within this functionally significant region constitutes the significant structural element shared by each of these isogenes.

For the foregoing reasons, Applicants submit that the Markush group of β_2 AR isogenes in claims 1, 3, 4, 29-31, and 33 has unity of invention, and therefore the current requirement for restriction is improper.

Respectfully submitted,



Matthew M. Catlett
Registration No. 44,067
Genaissance Pharmaceuticals, Inc.
Five Science Park
New Haven, CT 06511
203.773.1450
203.492.4474 (fax)